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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,372	11/21/2003	Gary A. Dahl	EPICEN-09584	3663
23535 7590 06/01/2007 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER HUTSON, RICHARD G	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/719,372

Applicant(s)

DAHL ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-205 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 172-205 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants cancellation of claims 1-171 and the addition of new claims 172-205, in the paper of 7/24/2006, are acknowledged. Claims 172-205 are at issue and are present for examination.

Election/Restrictions

Applicant's election without traverse of Group I, corresponding to original claims 1-45, 80-99, 108-144, in the paper of 7/24/2006, is acknowledged. Applicant's further election with traverse of groups A, F and K, in the paper of 10/27/2006, is also acknowledged. The traversal of the above sub-groups is on a number of different grounds. Applicants argue that the statutory basis of restriction is found in 35 U.S.C. 121 and that this section as well as the MPEP, section 808, only allows restriction of distinct inventions that are claimed. Applicants further submit that the legal support cited by the examiner relates to species, not a Group election. Applicants further argue that the restriction is improper as being overly burdensome on applicants if maintained as the claims are not drawn to unrelated nucleic acid sequences but instead the claims are drawn to general methods, a general kit and one general composition. Finally applicants submit that the restriction is not proper even as a species election because the examiner has not explained why each invention as claims is independent or distinct from each other and why there would be a serious burden on the examiner if the restriction were not required.

Applicant's complete traversal of the previous restriction requirement is acknowledged. First, it is noted that the restriction requirement was originally made in

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the office action mailed to applicants on 4/20/2006. In this office action the claims were restricted into a number of different groups and sub-groups. In response to this restriction applicants elected Group I and cancelled all of the dependent claims which specifically recited the referred to elected species. Such was done without making the required election. This action was improper, even if the restriction requirement is traversed. Applicant's subsequent complete election in the paper of 10/27/2006 is acknowledged.

Applicants complete traversal is acknowledged and has been carefully considered, however is found no persuasive for the reasons stated previously and repeated herein.

With respect to applicants argument that 35 U.S.C. 121, section 808 of the MPEP only allows restriction of distinct inventions that are claimed, applicants are reminded that claims to the independent and distinct inventions that were identified in the previous restriction requirement existed at the time that this requirement was initially made. Applicants subsequent canceling of these claims does not make the inventions or the requirement for an election in response to the restriction requirement go away. Such is necessary for the proper search and examination of the subject claims as well as because as applicants are aware these claims or the referred to subject matter may reappear at any time.

With respect to applicants additional points that the legal support cited by the examiner relates to species, and not a Group election and the restriction is improper as being overly burdensome on applicants if maintained as the claims are not drawn the

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claims are not drawn to unrelated nucleic acid sequences but instead the claims are drawn to general methods, a general kit and one general composition, applicants points are not persuasive as the claimed subject matter does encompass the patentably independent and distinct subject matter as previously pointed out in the restriction requirement. As applicant has cancelled the claims drawn to the individual species and applicants maintain that the current pending claims are drawn to "general methods" which encompass these "species", applicants claims will be examined to the point of the determination of patentability or unpatentability. Thus the restriction requirement does not effect the determination of these general method claims.

With respect to applicants traversal on the basis that it has not been explained why each invention as claimed is independent or distinct from each other and why there would be a serious burden on the examiner if the restriction were not required, applicants is reminded that it was previously stated that each of these inventions related to the different methods of use of the different SEQ ID Nos and the different RNAP are unrelated as the different inventions represent structurally different polypeptides and polynucleotides encoding them and thus different methods.

The above withstanding, given the cancellation of claims 1-171 and the addition of new claims 172-205, the current claims 172-205, which applicants submit should be grouped with previous Group I, have been restricted as follows:

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I_A. Claims 172-197, drawn to a method of making an RNA product, classified in class 435, subclass 91.1.
- II_A. Claims 198-200, drawn to a method for obtaining a substrate for transcription and obtaining a transcription product corresponding to a target sequence using a T7-type RNAP that binds a double-stranded promoter, classified in class 435, subclass 91.1.
- III_A. Claims 201-205, drawn to method for cloning a target sequence in a target nucleic acid, classified in class 435, subclass 91.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions (I_A)-(III_A) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods, (I_A)-(III_A), comprise different steps, employ different mechanisms, use different substrates and catalysts and result in different products.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

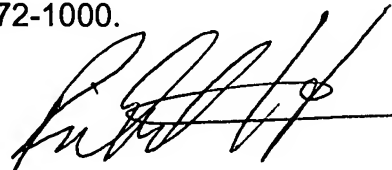
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'R. G. Hutson', written over a horizontal line.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
5/29/2007